

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Yukoh Sakata, et al.

Serial No.: 10/539,021

Group Art Unit: 1615

Filed: January 30, 2006

Examiner: Sasan, Aradhana

For: LIGHT-SHIELDING AGENT AND FILM-FORMING COMPOSITION

DECLARATION UNDER 37 CFR §1.132

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

I, Yukoh Sakata, hereby declare and state that:

1. I am a citizen of Japan, residing at 1624 Shimokotachi, Koda-cho, Akitakata-shi, Hiroshima, 739-1195, Japan.

2. I am one of the inventors of the subject application, and I am fully familiar with the subject matter thereof as well as the references relied upon by the Examiner in the prosecution of this application.

3. I obtained a Doctoral degree from Hoshi University, Department of Pharmaceutics, School of Pharmacy, in September, 2007, whereat I performed a kinetic study on crystal water affecting pharmaceutical properties of hydrate and anhydrate tablets.

4. I am currently employed by Wakunaga Pharmaceutical Co., Ltd., and began working for Wakunaga Pharmaceutical Co., Ltd., in April 1992, whereat I have engaged in research and development relating to developing the formulation.

5. I conducted the following comparative test in order to show the difference between the present invention and the cited reference, namely, US 3,049,433 (Butler et al.).

METHOD:

I. Preparation of aqueous solution or dispersion of each cellulose derivative.

Hydroxypropyl cellulose (HPC) was dissolved in purified water to obtain an 8% (w/w) aqueous solution (Sample 1).

Hydroxypropylmethyl cellulose (HPMC) was dissolved in purified water to obtain an 8% (w/w) aqueous solution (Sample 2).

Hydroxyethyl cellulose (HEC) was dissolved in purified

water to obtain a 1% (w/w) aqueous solution (Sample 3). Please note that the highest concentration of HEC in the aqueous solution without gelating was 1% (w/w).

Carboxymethylcellulose (CMC) was dispersed in purified water to obtain a 3% (w/w) dispersion (Sample 4). Please note that CMC could not be dissolved in water.

(Please note that carboxymethyl hydroxyethyl cellulose disclosed in the cited reference could not be obtained, and therefore was not examined.)

## II. Adding calcium chloride

Calcium chloride was added to Samples 1, 2, and 4, to obtain Samples 5, 6, 8, respectively. The content of calcium chloride in the samples was 3% (w/w).

Calcium chloride was added to Sample 3 to obtain Sample 7. The content of calcium chloride in the sample was 1% (w/w).

## III. Forming film

20 g of each sample was put into a dish, and dried at 120°C for 1 hour.

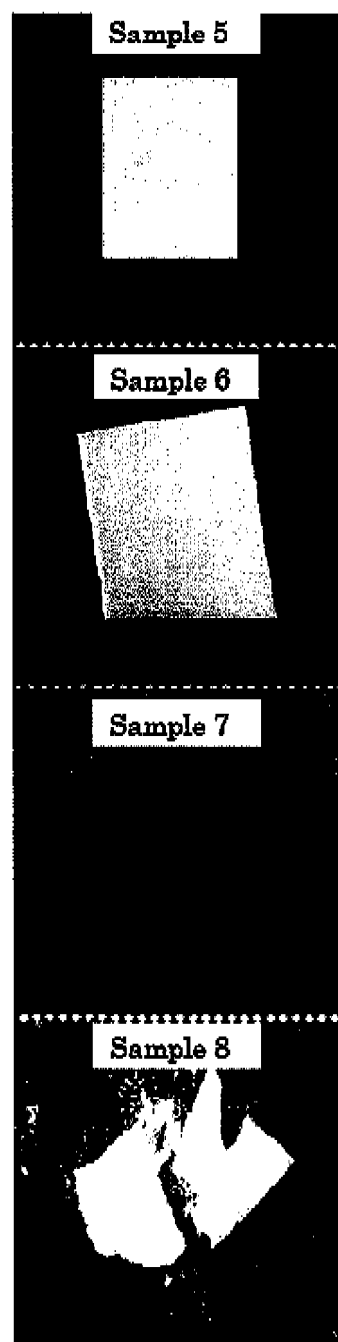
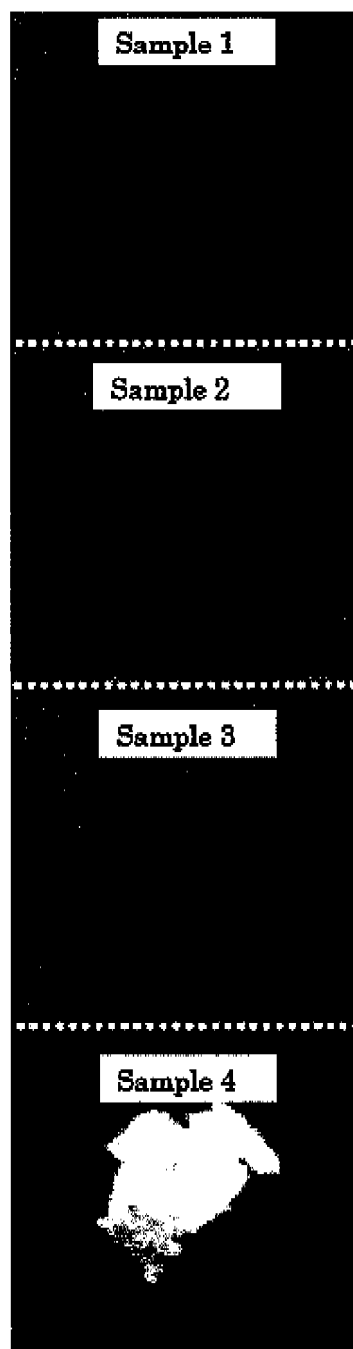
## RESULTS:

Although Samples 1 and 2 formed transparent sheets, Samples 5 and 6 formed white sheets.

Sample 3 had high flexibility, the high flexibility making it difficult to form a sheet. Neither Sample 3 nor 7 could not

form a white sheet.

Samples 4 and 8 did not form a film, but formed white agglomerates of CMC powders.



**CONCLUSION:**

The above-mentioned results show that calcium chloride forms white film when used with HPC or HPMC as claimed in the present invention, but does not form a white film when used with HEC or CMC as taught by Butler et al.

7. I understand fully the content of this declaration.

8. I, Yukoh Sakata, the undersigned declarant further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001, of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signed this 31 day of July, 2009.

Yukoh Sakata

(Yukoh Sakata)